



MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

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Hours of operation 24 Hours
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| | |
|-----------------|---|
| Product name | Equimax® |
| Chemical family | Pyrazinoisoquinoline derivative/ Avermectin macrocyclic lactone |
| Therapeutic use | Anthelmintic/ Antiparasitic |
| Description | Odorless, white, thick, smooth paste |

SECTION 2 - COMPOSITION

| <u>Ingredient</u> | <u>CAS Number</u> | <u>Amount</u> |
|-------------------------|-------------------|---------------|
| Praziquantel* | 55268-74-1 | 14.03% |
| Ivermectin* | 70288-86-7 | 1.87% ** |
| Proprietary Ingredients | Not assigned | 84.1% |

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. The ingredients in this formulation are being held as trade secret. In the event of a medical emergency or for use of this MSDS outside the United States, contact the emergency telephone number listed in Section 1 for ingredient information.

** Ivermectin is a mixture of Ivermectin component B_{1α} (70161-11-4) and Ivermectin component B_{1β} (70209-81-3)

SECTION 3 - HAZARDS IDENTIFICATION

| | |
|----------------------|---|
| Signal word | WARNING! |
| Statements of hazard | TOXIC IF SWALLOWED POSSIBLE RISK OF HARM TO THE UNBORN CHILD |
| Eye effects | May cause irritation based on components. |
| Skin effects | May cause irritation based on components. |
| Inhalation effects | Not expected due to physical form. |
| Ingestion effects | May be harmful if swallowed. See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section. |

SECTION 3 - HAZARDS IDENTIFICATION ... continued

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| Known clinical effects | Adverse effects most frequently reported with the use of praziquantel include headache, diarrhea, dizziness, drowsiness, weakness, abdominal discomfort, nausea, and vomiting. Adverse effects associated with the clinical use of ivermectin may include joint or muscle pain, dizziness, fever, headache, skin rash, itching, fast heartbeat, and swelling of face or extremities. |
| Other potential health effects | Animal studies with ivermectin have shown a potential to cause adverse effects on the fetus. |
| NOTE: | This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace. |

SECTION 4 - FIRST AID MEASURES

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| Skin | Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention. |
| Eyes | Immediately flush eyes with water for at least 15 minutes. Get medical attention. If irritation occurs or persists, get medical attention. |
| Inhalation | Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately. |
| Ingestion | Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. |

SECTION 5 - FIRE FIGHTING MEASURES

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| Fire fighting instructions | Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance. |
| Extinguishing media | Water spray, carbon dioxide, dry chemical or foam. |
| Flash point | No data available |
| Hazardous combustion products | Carbon monoxide and carbon dioxide |

SECTION 6 - ACCIDENTAL RELEASE MEASURES

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|--------------------|---|
| General | Review Sections 3, 8 and 12 before proceeding with clean up. |
| Small spill | Use non-combustible material to absorb spill; then place in a suitable, labeled recovery container. Clean spill area thoroughly. Prevent discharge to drains. |
| Large spill | Collect spill with a non-combustible absorbent material. Transfer all waste to a labeled container and move it to a secure holding area. Prevent discharge to drains. |

SECTION 7 - HANDLING AND STORAGE

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| General handling | Use only in a well-ventilated area. Avoid contact with eyes. Avoid contact with skin and clothing. Wash thoroughly after handling. |
| Storage conditions | Store in a cool, dry, well-ventilated area. Protect from light. Keep container tightly closed when not in use. |
| Temperature range for storage | <30°C (<86°F) |

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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| Ventilation | Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. Local and general ventilation should be used as necessary, when handling this material in bulk. |
| Respiratory protection | Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk. |
| Eye protection | Safety glasses or goggles |
| Skin protection | Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. |
| Hand protection | Rubber gloves |

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

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|--------------------------|----------|
| Physical form | Paste |
| Color | White |
| Odor | Odorless |
| Molecular weight | Mixture |
| Molecular formula | Mixture |

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ... continued

| | |
|---------------------------|-------------------|
| pH | Not applicable |
| Boiling point | Not applicable |
| Melting point | Not applicable |
| Density | No data available |
| Vapor pressure | No data available |
| Water solubility | No data available |
| Solvent solubility | No data available |

SECTION 10 - STABILITY AND REACTIVITY

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|---|---|
| Reactivity | Stable |
| Conditions to avoid | None known |
| Incompatibilities | None known |
| Hazardous decomposition products | Thermal decomposition products may include carbon monoxide and carbon dioxide |
| Hazardous polymerization | Will not occur |

SECTION 11 - TOXICOLOGY INFORMATION

| | |
|---------------------------|---|
| Toxicology summary | The information included in this section describes the potential hazards of the active ingredients. |
|---------------------------|---|

Acute toxicity

| <u>Compound</u> | <u>Type</u> | <u>Route</u> | <u>Species</u> | <u>Result</u> |
|-----------------|------------------|--------------|----------------|---------------|
| Praziquantel | LD ₅₀ | Oral | Rat | 2840 mg/kg |
| Ivermectin | LD ₅₀ | Oral | Rat | 10 mg/kg |

Eye May cause eye irritation based on components.

Skin May cause skin irritation based on components.

Inhalation No data available

Ingestion See Acute toxicity table.

Mutagenicity Praziquantel was not mutagenic in a number of mammalian cell assays. Ivermectin showed no evidence of mutagenic activity in bacterial or mammalian cells *in vitro*.

Subchronic effects No data available

SECTION 11 - TOXICOLOGY INFORMATION ... continued

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| Chronic effects/ carcinogenicity | Long term carcinogenicity studies with praziquantel in rats and golden hamsters did not reveal any carcinogenic effect. |
| Carcinogen status | None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. |
| Reproductive effects | Reproduction studies have been performed in rats and rabbits at doses up to 40 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to praziquantel. An increase of the abortion rate was found in rats at three times the single human therapeutic dose. Ivermectin had no adverse effects on the fertility in rats in studies at repeated doses of up to 3 times the maximum recommended human dose of 200 µg/kg. |
| Teratogenicity | Praziquantel did not cause teratogenicity in rats, mice, or rabbits. Ivermectin has been shown to be teratogenic in rats, rabbits, and mice at or near maternotoxic dose levels. Mice are the most sensitive species to the effects of ivermectin with maternotoxicity at a dose of 200 µg/kg/day and teratogenicity at 400 µg/kg/day. In rabbits 6000 µg/kg/day was maternotoxic and teratogenic, and teratogenicity was also evident at a dose of 3000 µg/kg/day. The threshold for both maternotoxicity and teratogenicity in rats was 10,000 µg/kg/day. |

SECTION 12 - ECOLOGICAL INFORMATION

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|--|--|-------------|----------------|
| Environmental overview | As with other members of the avermectin family, ivermectin is highly toxic to fish and certain aquatic organisms. However, once in contact with soil, it is tightly bound and does not readily desorb. It is unlikely to reach groundwater and is also biodegradable by soil microflora. | | |
| Mobility, persistence, and degradability: | Avermectin compounds may bind tightly to soil upon contact and become inactive over time. | | |
| Bioaccumulation and toxicity: | See aquatic toxicity data, below. | | |
| Aquatic toxicity | <u>Compound</u> | <u>Type</u> | <u>Species</u> |
| | Ivermectin | LC50/48h | Rainbow Trout |
| | | | <u>Result</u> |
| | | | 0.000025 mg/L |

SECTION 13 - DISPOSAL INFORMATION

| | |
|---------------------------|--|
| Disposal procedure | Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this mixture. |
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SECTION 14 - TRANSPORTATION INFORMATION

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| General shipping instructions | This material is regulated for transportation as a hazardous material/dangerous good. Non-regulated in non-bulk packagings transported by motor vehicles, rail cars or aircraft (49CFR 171.4(c)). |
| IMDG proper shipping name | Environmentally hazardous substance, solid, n.o.s. (ivermectin), Marine Pollutant |
| IMDG Identification No. | UN 3077 |
| IMDG hazard class | 9 |
| IMDG packing group | III |

SECTION 15 - REGULATORY INFORMATION

EU Classification Toxic; Dangerous for the Environment

EU Labelling T

EU Label Pictogram(s)



Risk phrases R25 - Toxic if swallowed.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S61 - Avoid release to the environment. Refer to special instructions/safety data sheets.

Canadian WHMIS Class D, Division 1, Subdivision A
Class D, Division 2, Subdivision A

SECTION 16 - OTHER

Disclaimer Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.